406 S. Pennsylvania Ave • Centre Hall, PA 16828
(814) 364-1344 • fax (814) 364-4431
info@paorganic.org www.paorganic.org

Comments to the National Organic Standards Board
April 10, 2006

Comments on the Sunset Review of Processing Materials

General comments:
Pennsylvania Certified Organic appreciates the extensive review performed by the NOSB in a relatively short time in order to accomplish the required sunset review of the initial National List materials. We urge the Board to take the time to evaluate the process to determine how to improve this required review in future rounds of review. In particular, the public only had 30 days to file comments on the entire list last summer, and the NOSB has had less than one year to review all the outstanding materials. This does not permit careful review or needed research on a number of complex issues: a longer timeline is essential if the reviews are to be meaningful. PCO urges NOSB and NOP to start now on the required reviews for the materials that were added to the National List in 2003, and post a notice for sunset comments as soon as possible.

The Board also needs to seriously reconsider its stated policy of refusing to make any changes in material annotations during the sunset review. The Board has called for a number of technical changes to annotations since the rules were published in Dec. of 2000, and the sunset review would seem to be an ideal chance to incorporate these needed corrections. For instance, in the case of chlorine, there is a widely acknowledged discrepancy between the original NOSB recommendation and the language of the 2000 rule. The NOSB recommended a clarification in the annotation for all three forms in May 2003. Although these changes were never addressed by NOP, it is logical and clearly needed that these corrections be made in the context of regular sunset review.

1. Nonsynthetic Colors
The Handling committee has recommended that "colors (nonsynthetic sources)" remain on the National List at 205.605 as currently described as "nonorganic, nonagricultural substances" permitted in handling with no restrictions. However, as the technical review provided indicates, there is no NOP definition for "nonsynthetic colors", no review of manufacturing processes, and no standard of identity provided by FDA. What does the NOSB consider a nonsynthetic color? While natural flavors were the subject of an early detailed recommendation by NOSB in 1995, [1] there was no such review for flavors. Natural colors appeared in the 1997 proposed rule, were removed after public comment (including the NOSB) and not listed in the May 2000 proposed rule, but reappeared in the final Dec. 2000 rule.

[1] The Use of Natural Flavors in Organic Foods, NOSB Final Recommendation Addendum No. 14, Oct. 31, 1995.

The Handling committee states that: "This technical review offered no information that would suggest that either non-synthetic colors or flavors are inconsistent with organic practices." The recommendation further implies that the current FDA food additive pre-market review process is adequate to address any concerns related to criteria for organic production. Although FDA reviews additives for safety and toxicity, this does not include all criteria that organic food is required to meet. There has been no information provided to indicate review under the OFPA criteria or under the processing criteria in 205.600(b).

The NOP has consistently stated that any substance included as a category or specific item on the National List includes all components used to manufacture that generic substance.[2] If NOSB is not reviewing individual colors, then it must be presumed that all solvents and other synthetics used in formulating colors claimed as nonsynthetic are also considered approved.

The technical overview of colors notes that FDA characterizes colors as either "exempt from certification" or those that require "batch certification." "Color additives that are exempt from certification include pigments derived from natural sources such as vegetables, minerals or animals, and man-made counterparts of natural derivatives."[3] Does NOSB intend that all colors exempt from certification be considered nonsynthetic?

Exempt colors include:

> Annatto extract, Astaxanthin, Dehydrated beets (beet powder), Ultramarine blue Salt for animal feed, Canthaxanthin, Caramel, ß-Apo-8'-carotenal, ß-Carotene, Conchineal extract; Sodium copper chlorophyllin, Toasted partially defatted cook cottonseed flour, Ferrous gluconate, Ferrous lactate, Grape color extract, Grape skin extract (enocianina), Haematococcus algae meal, Synthetic iron oxide, Fruit juice, Vegetable juice, Dried algae meal, Tagetes (Aztec marigold meal and extract), Carrot oil, Corn endosperm oil , Paprika , Paprika oleoresin , Phaffia yeast , Riboflavin, Saffron, Titanium dioxide, Turmeric, and Turmeric oleoresin.

The specific 21 CFR references to these substances give an idea of the manufacturing process, for example annatto (21 CFR 73.30) is permitted to include acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene to be used as solvents. For beta-carotene**,** 21 CFR 73.95 states: "(a) Identity. (1) The color additive is [beta]-carotene prepared synthetically or obtained from natural sources."

Does NOSB intend that certifiers review colors on a case-by-case basis, and apply their own judgment on the extraction or formulation method? If so, further guidance would be helpful on which colors are considered nonsynthetic, and whether synthetic solvents and additives can be used as carriers.

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[2] http://www.ams.usda.gov/nop/Q&A.html National List of Allowed and Prohibited Substances
Q: Do nonagricultural substances included on the National List of Allowed and Prohibited Substances have to be produced without the use of volatile synthetic solvents? A: no……

[3] FDA, Food Color Facts 1993 http://www.cfsan.fda.gov/~lrd/colorfac.htm

Many of these exempt colors are derived from agricultural substances. Can paprika or turmeric be permitted as coloring additives without an attempt as sourcing organic forms?

- **Colors (nonsynthetic) should be removed from the National List**. Specific colors can be petitioned and reviewed to consider their manufacturing process. At a minimum, colors could be listed at 205.606, as non-organic agricultural substances, with the annotation, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservatives. This would require that organic forms be used when commercially available.

2. Nonsynthetic Flavors

Unlike natural colors, natural flavors do have an FDA definition, which is cited in the TAP review. NOSB further restricted the types of additives used in formulation of nonsynthetic flavors. Interestingly, the TAP review also cites the original NOSB recommendation from 1995:

"Additionally the following conditions must be satisfied:

> Manufacturers must provide written documentation in their Organic Handling Plan, which shows that efforts were made toward the ultimate production of an organic natural flavor as listed in the stepwise progression below:
> - Natural flavor constituents and non-synthetic carrier base and preservative agents
> - Organic flavor constituents, organic carrier base, and organic preservative agents
> - Organic flavor constituents extracted using organically produced solvent organic carrier base, and organic preservative agents."

This requirement for improvement in sourcing of organic flavors was not incorporated into the final rule. By renewing the current listing, NOSB fails to acknowledge the need for continuous improvement in sourcing of organic ingredients, as documented in the organic system plan. At this time, there are many flavors available in certified organic forms, but there is no requirement for their use. The sunset review is an excellent time to remedy this situation.

- **Flavors, nonsynthetic should be listed in 205.606 – as nonorganically produced agricultural ingredients allowed as ingredients.** This will mean that organic forms should be used when commercially available.

3. Chlorine products for use in handling applications

The handling committee has recommended renewing the existing listing for chlorine. However, as the NOSB previously noted, in their recommendation from May 2003[4], the NOP standard is not clear.

> "The National List contains annotations for the use of chlorine compounds which do not accurately convey the annotations recommended by the NOSB. As a result, the Questions and Answers posted on the NOP website focus on measuring chlorine levels at the effluent or discharge site of the facility, rather than at the point where the chlorine solution contacts organic food. This has led to confusion among processors, certifying agents, and inspectors, and has led to inconsistent application of the NOP rule. The NOSB Processing Committee recommends that

[4] http://www.ams.usda.gov/nosb/FinalRecommendations/May03/Chlorine.pdf

the annotations be corrected to accurately reflect the original NOSB recommendation, that the Q & A's be re-phrased to provide accurate and consistent guidance, and that the review of chlorine should be prioritized in the re-review process in light of new information about the use of chlorine compounds."

The TAP review and the committee reports have not considered this 2003 recommendation which recommends that the annotation at 205.605(b) be adjusted to say:

> Chlorine materials - ~~disinfecting and sanitizing food contact surfaces, Except, That,~~ residual chlorine levels in the water <u>in direct crop or food contact</u> shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
> .

The recent TAP review did not consider that the current listing allows applications where chlorine is used in direct contact with organic food products (produce washing, milk processing pipelines). This was likely due to a literal reading of the current annotation, which implies that it may only be used for equipment cleaning. The NOSB further clarified in proposed corrections to the NOP Questions and Answers that chlorine should be measured in water in last contact with organic crops, permitting a rinse with potable water. This practice will allow for most standard use of chlorine to sanitize produce at levels commonly used in the 50-100 ppm range.

One problem with this proposal is that organic dairy producers and processors are required to follow state laws adopted in congruence with FDA's model Pasteurized Milk Ordinance[5]. This requires the use of FDA approved sanitizers, following label directions, or alternative use of steam or hot water at prescribed temperatures. Steam and hot water for 170-200 degrees for five minutes throughout the whole system is not practical or safe in some situations. Chemical sanitizers are considered antimicrobial pesticides, and must be registered by the EPA, and are subject to label review and approval. Chlorine products labeled for use in dairy sanitation will typically state that they must be used at levels of 50-100 ppm and must not be rinsed. These label directions are considered binding for dairy applications.[6] This conflicts with the NOSB recommendation that a maximum of 4ppm be present in the final rinse. Peracetic acid products

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[5] http://www.cfsan.fda.gov/~ear/pmo03toc.html
Appendix F. Sanitization
I. METHODS OF SANITIZATION

CHEMICAL
Certain chemical compounds are effective for the sanitization of milk containers, utensils and equipment. These are contained in 21 CFR 178.1010 and shall be used in accordance with label directions.
STEAM
When steam is used, each group of assembled piping shall be treated separately by inserting the steam hose into the inlet and maintaining steam flow from the outlet for at least five (5) minutes after the temperature of the drainage at the outlet has reached 94°C (200°F). The period of exposure required here is longer than that required for individual cans, because of the heat lost through the large surface exposed to the air. Covers must be in place during treatment.
HOT WATER
Hot water may be used by pumping it through the inlet, if the temperature at the outlet end of the assembly is maintained to at least 77°C (170°F) for at least five (5) minutes.

[6] Pers. communication, Dr. Scott Rankin, U. of WI-Madison, Department of Food Science. sarnkin@facstaff.wisc.edu

are a viable alternative for this use, however they have not yet been included on the National List.

- **NOSB should consider amending the listing as follows in order to be consistent with state regulations and to clarify the confusing and inconsistently applied existing annotation.**

  Chlorine materials - ~~disinfecting and sanitizing food contact surfaces, Except, That,~~ residual chlorine levels in the water in direct crop or food contact shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except when mandated by state or federal regulations, in which case the minimum required level should be used.

Respectfully submitted,
Emily Brown Rosen
Materials Review Manager
Pennsylvania Certified Organic